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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,008

03/16/2005

Dann LeRoy Parker

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EXAMINER

SHAMEEM, GOLAM M

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

11/02/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/528,008

**Applicant(s)**

PARKER ET AL.

**Examiner**

Golam M. M. Shameem, Ph.D.

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 9-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>06/09/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Priority*

This application is a 371 of PCT/US03/28855 09/15/2003, which claims benefit for domestic priority under 35 U.S.C. § 119(e) [to a provisional application 60/412,093 09/19/2002], is acknowledged.

### *Status of Claims*

Claims 1-20 are currently pending in the application.

Receipt is acknowledged of amendment / response filed on October 15, 2007 and that has been entered.

Claims 9-20 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142 (b) as being drawn to a non-elected subject matter.

### *Information Disclosure Statement*

Receipt is acknowledged of Information Disclosure Statement (IDS), filed on 06/09/2005, which has been entered in the file.

### *Response to Election/Restriction*

In response to the restriction requirement, Applicants have elected Group I, (which includes claims 1-8 drawn to a compound and composition) **without** traverse is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, and therefore, the requirement for restriction is still deemed proper and is made FINAL.

Applicants preserve their right to file a divisional on the non-elected subject matter.

As set forth in the restriction requirement and an election of a single compound (or set of compounds), the invention will encompass all compounds that fall within the scope of the search is as follows:

A compound of the formula as shown in claim 1 wherein:

X is limited to O,

Y is as claimed,

Z is as claimed,

R<sup>3</sup> is as claimed except "hydrogen" and "C<sub>1-10</sub>alkyl",

R<sup>4</sup> is as claimed except "fluoro",

R<sup>5</sup> is as claimed,

R<sup>6</sup> is as claimed except "hydrogen",

R<sup>7</sup> is as claimed except "hydrogen" and ,

R<sup>10</sup> is as claimed except "hydrogen" and "C(=O)R<sup>b</sup>".

As a result of the election and the corresponding scope of the compound identified, claims 9-20 and the remaining subject matter of claims 1-8 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn subject matter of claims 9-20 is properly restricted as it differs materially in structure and in element from the elected subject matter supra so as to be patentably distinct there from.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1626

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. § 102(b) as being anticipated by Stetter *et al* (1984). Applicant claims estrogen receptor modulator compounds, composition and the methods of uses thereof. Stetter *et al* also disclose the synthesis of substituted inden compounds and at least one of them anticipates the instantly claimed invention wherein X is O, Y is CR<sup>1</sup>R<sup>2</sup> (wherein R<sup>1</sup>R<sup>2</sup> are both hydrogen), Z is CR<sup>8</sup>R<sup>9</sup> (wherein R<sup>8</sup>R<sup>9</sup> are both hydrogen), R<sup>4</sup>-R<sup>7</sup> are all hydrogen, R<sup>3</sup> is C<sub>1-10</sub>alkyl (such as, Et), and R<sup>10</sup> is hydrogen [STN International, HCAPLUS database, RN number, 89506-52-5, a copy is provided with this Office action], which reads on the instantly claimed compound.

Kende *et al* (1974) also disclose the synthesis of substituted inden compounds and at least one of them anticipates the instantly claimed invention wherein X is O, Y is CR<sup>1</sup>R<sup>2</sup> (wherein R<sup>1</sup>R<sup>2</sup> are both hydrogen), Z is CR<sup>8</sup>R<sup>9</sup> (wherein R<sup>8</sup>R<sup>9</sup> are both hydrogen), R<sup>4</sup>-R<sup>7</sup> are all hydrogen, R<sup>3</sup> is hydrogen, and R<sup>10</sup> is C(=O)R<sup>b</sup> [wherein R<sup>b</sup> is O(C<sub>1-4</sub>alkyl)] [STN International, HCAPLUS database, RN number, 53877-38-6, a copy is provided with this Office action], which reads on the instantly claimed compound.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting, as being unpatentable over claims 1-8 of US 7,087,599 and also over 1-10 of US 7,157,604, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to the same art recognized subject matter. The compounds and compositions taught by US '599 and US '604 are similar to instant application because a reference anticipating one set of claim will render the other obvious and it would have been obvious to one of ordinary skill in the art at the time of the invention was made since prior art teaches the generic compounds and compositions which are similar to the instantly claimed invention.

The subject matter claimed in the instant application is fully disclosed and covered by US '599 and US '604. Therefore, the disclosure of prior art that teaches many permutation and combination substitutions (including various Markush variable substitutions, such as R<sup>3</sup>, X, Y, and Z etc), which would easily place Applicants invention in possession of the public at the time of Applicants invention was filed. The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The claimed compounds and compositions are so closely related structurally to the homologous and /or analogous compounds and compositions of the reference as to be structurally obvious therefore in the absence of any unobviousness or unexpected properties. Moreover, any other differences are but obvious structural modifications, which would be apparent to one skilled in the chemical art that can use similar substitutions, would expect to have the same or essentially the same results. Therefore, in

looking at the instant claimed compounds and salts as a whole, the claimed compounds and compositions would have been suggested to one skilled in the art unless unobvious or unexpected results can be shown.

### *Objections*

Claims 1-8 are objected to for containing non-elected subject matter. The claims should be amended to exclude non-elected subject matter and within the scope of elected compound.

### *Telephone Inquiry*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone number for this Group is (571) 273-8300.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet

Art Unit: 1626

e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.

Golam M M Shameem, Ph.D.  
Primary Patent Examiner  
Art Unit 1626  
Technology Center 1600

A handwritten signature in black ink, appearing to read 'M. M. Shameem', with a large, stylized initial 'M'.

**GOLAM M. M. SHAMEEM, PH.D**  
**PRIMARY EXAMINER**